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Proposed Registration Decision PRD2012-03

Mono- and Di-Potassium Salts of Phosphorous Acid

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Overview

Proposed Registration Decision for Mono- and Di-Potassium Salts of Phosphorous Acid

Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Mono- and Di-Potassium Salts of Phosphorous Acid and Confine, containing the technical grade active ingredient mono- and di-potassium salts of phosphorous acid, for suppression of late blight and pink rot on harvested potato tubers.

Mono- and Di-Potassium Salts of Phosphorous Acid (Registration Number 29099) and Confine (Registration Number 29100) are conditionally registered in Canada. The detailed review for Mono- and Di-Potassium Salts of Phosphorous Acid and Confine can be found in Evaluation Report ERC2010-09 - *Mono- and Di-Potassium Salts of Phosphorous Acid*. The current applications were submitted to convert Mono- and Di-Potassium Salts of Phosphorous Acid and Confine from conditional registration to full registration.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

This Overview describes the key points of the evaluation, while the Science Evaluation section provides detailed technical information on the human health, environmental and value assessments of Mono- and Di-Potassium Salts of Phosphorous Acid and Confine.

What Does Health Canada Consider When Making a Registration Decision?

The key objective of the *Pest Control Products Act* is to prevent unacceptable risks to people and the environment from the use of pest control products. Health or environmental risk is considered acceptable[1] if there is reasonable certainty that no harm to human health, future generations or the environment will result from use or exposure to the product under its proposed conditions of registration. The Act also requires that products have value[2] when used according to the label directions. Conditions of registration may include special precautionary measures on the product label to further reduce risk.

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1 "Acceptable risks" as defined by subsection 2(2) of the *Pest Control Products Act*.

2 "Value" as defined by subsection 2(1) of the *Pest Control Products Act*: "the product's actual or potential contribution to pest management, taking into account its conditions or proposed conditions of registration, and includes the product's (*a*) efficacy; (*b*) effect on host organisms in connection with which it is intended to be used; and (*c*) health, safety and environmental benefits and social and economic impact."

To reach its decisions, the PMRA applies modern, rigorous risk-assessment methods and policies. These methods consider the unique characteristics of sensitive subpopulations in humans (e.g. children) as well as organisms in the environment (e.g. those most sensitive to environmental contaminants). These methods and policies also consider the nature of the effects observed and the uncertainties when predicting the impact of pesticides. For more information on how the PMRA regulates pesticides, the assessment process and risk-reduction programs, please visit the PMRA's website at healthcanada.gc.ca/pmra.

Before making a final registration decision on mono- and di-potassium salts of phosphorous acid, the PMRA will consider all comments received from the public in response to this consultation document[3]. The PMRA will then publish a Registration Decision[4] on mono- and di-potassium salts of phosphorous acid, which will include the decision, the reasons for it, a summary of comments received on the proposed final registration decision and the PMRA's response to these comments.

For more details on the information presented in this Overview, please refer to the Science Evaluation section of this consultation document.

What Is Mono- and Di-potassium Salts of Phosphorous Acid?

Mono- and di-potassium salts of phosphorous acid, or phosphorous acid, is a fungicide active ingredient belonging to Group 33 and is classified as a phosphonate. The mode of action of phosphorous acid is both direct and indirect. Mono- and di-potassium salts of phosphorous acid is the active ingredient in the fungicide Confine, which is registered for suppression of late blight and pink rot on harvested potato tubers.

Health Considerations

Can Approved Uses of Mono- and Di-Potassium Salts of Phosphorous Acid Affect Human Health?

Mono- and di-potassium salts of phosphorous acid is unlikely to affect human health when used according to label directions.

Exposure to mono- and di-potassium salts of phosphorous acid may occur when handling and applying the product. When assessing health risks, two key factors are considered: the levels where no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which the exposure is well below levels that cause no effects in animal testing are considered acceptable for registration.

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3 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

4 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Mono- and di-potassium salts of phosphorous acid is of low toxicity by the oral, dermal and inhalation routes, and only minimally irritating to the eyes. The precautionary label statement indicating that contact with eyes must be avoided, and the personal protective equipment statement that applicators and other handlers must wear protective eyewear are effective mitigative measures to reduce the risk associated with the use of this chemical.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Mono- and di-potassium salts of phosphorous acid is of low acute toxicity by the oral, dermal and inhalation routes. It is minimally irritating to the eyes, non-irritating to the skin and is not a skin sensitizer. The available information suggests that it is unlikely to have any short-term or prenatal developmental effects, as well as any significant genotoxic effects.

Dietary risk to humans is considered negligible based on the intended use, method of application, low application rate, and low toxicity of the end-use product. The available literature suggests that there is no toxicological concern from ingestion of the end-use product residues.

It is anticipated that the proposed use of mono- and di-potassium salts of phosphorous acid in Canada on stored potatoes will not pose a risk to any segment of the population, including infants, children, adults and seniors, when potatoes are subjected to the normal process of washing, peeling and cooking for human consumption. In the United States, phosphorous acid has been designated Generally Regarded As Safe (GRAS) and the potassium salts of phosphoric acid have been exempted from the requirement of tolerance in and on all food commodities when used as an agricultural fungicide on food crops. The United States Environmental Protection Agency (USEPA) introduced an initiative whereby an exemption from the requirement of a tolerance were established for ammonium, sodium, and potassium salts of phosphorous acid on all food commodities to permit post-harvest application to stored potatoes at 35,600 ppm or less of phosphorous acid.

This end-use product will be used in a contained treatment area and will not be applied to water. No risk due to exposure from drinking water is anticipated.

Occupational Risks From Handling Mono- and Di-Potassium Salts of Phosphorous Acid

Occupational risks are not of concern when mono- and di-potassium salts of phosphorous acid is used according to label directions, which include protective measures.

Occupational exposure to mono- and di-potassium salts of phosphorous acid is expected to be minimal as application is done by automated enclosed spray chamber, which sprays newly-harvested potatoes when they pass along a conveyor belt towards storage bins. Precautionary statements on the label (for example, wearing of personal protective equipment and clothing) are considered adequate to protect individuals from any unnecessary risk due to exposure. Given the method of application and low toxicity of the end-use product, bystander exposure risk is anticipated to be negligible.

Environmental Considerations

What Happens When Mono- and Di-Potassium Salts of Phosphorous Acid Is Introduced Into the Environment?

Mono- and di-potassium salts of phosphorous acid is used in the formulation of Confine for the suppression of late blight and pink rot storage infection on harvested potato tubers. Since the end-use product will be used indoors on post-harvest potatoes, the risk to non-target organisms is considered to be negligible, when used according to the label. Because of the use pattern, Confine is unlikely to be introduced to the environment.

Value Considerations

What Is the Value of Confine?

Confine is a non-conventional and systemic fungicide to be used for post-harvest suppression of late blight and pink rot in potato tubers.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law.

The key risk-reduction measures being proposed on the label of Confine to address the potential risks identified in this assessment are as follows.

Key Risk-Reduction Measures

Human Health

Because mono- and di-potassium salts of phosphorous acid is used for formulating a commercial product, the statement on the technical label: "prevent access by unauthorized personnel" in the precaution section of the technical label will help mitigate the inappropriate use of the product, and help avoid accidental exposure. Other precautionary statements on the technical and end-use product labels, such as: "avoid breathing vapors or spray mist, avoid contact with eyes; remove contaminated clothing and wash clothing before use; applicators and other handlers must wear protective eyewear, long pants and long sleeved shirt, waterproof gloves, and shoes plus socks," should be effective in minimizing the potential for exposure.

Next Steps

Before making a final registration decision on mono- and di-potassium salts of phosphorous acid, the PMRA will consider all comments received from the public in response to this consultation document. The PMRA will accept written comments on this proposal up to 45 days from the date of publication of this document. Please forward all comments to Publications (contact information on the cover page of this document). The PMRA will then publish a Registration Decision, which will include its decision, the reasons for it, a summary of comments received on the proposed final decision and the Agency's response to these comments.

Other Information

When the PMRA makes its registration decision, it will publish a Registration Decision on mono- and di-potassium salts of phosphorous acid (based on the Science Evaluation section of this consultation document). In addition, the test data referenced in this consultation document will be available for public inspection, upon application, in the PMRA's Reading Room (located in Ottawa).

Science Evaluation

Mono- and Di-Potassium Salts of Phosphorous Acid

1.0 The Active Ingredient, Its Properties and Uses

For an assessment of the active ingredient and its properties, please refer to ERC2010-09 - *Mono- and Di-Potassium Salts of Phosphorous Acid.*

1.1 Directions for Use

For the post-harvest suppression of late blight (*Phytophthora infestans*) and pink rot (*P. erythroseptica*) on potato tubers, dilute Confine at 1:4.3 water ratio with application water. Apply 2 L of the mixture as a spray to 1000 kg of potatoes. Ensure complete and even coverage.

1.2 Mode of Action

The mode of action of phosphorous acid is both direct and indirect. It inhibits fungal growth in Oomycetes, a group of fungal-like organisms. In addition, there is also evidence that it stimulates the plant's natural defense response against pathogen attack. A major factor in the ability of phosphorous acid to control Oomycetes is its chemical stability within the plant. Phosphorous acid does not convert to phosphate and is not easily metabolized.

2.0 Methods of Analysis

For an assessment of the methods of analysis, please refer to ERC2010-09 - *Mono- and Di-Potassium Salts of Phosphorous Acid.*

3.0 Impact on Human and Animal Health

For an assessment of the impact on human and animal health, please refer to ERC2010-09 - *Mono- and Di-Potassium Salts of Phosphorous Acid.*

4.0 Impact on the Environment

For an assessment of the impact of mono- and di-potassium salts of phosphorous acid on the environment, please refer to ERC2010-09 - *Mono- and Di-Potassium Salts of Phosphorous Acid.*

5.0 Value

5.1 Effectiveness Against Pests

Claims of suppression of late blight and pink rot were supported based on the submitted data. Refer to ERC 2010-09 for review conclusions. Additional data were requested to demonstrate that Confine is still efficacious after common storage periods, i.e. four and eight months. One confirmatory trial from Prince Edward Island (2010) was provided to that effect. Tubers were inoculated with *P. erythroseptica* and *P. infestans*. High levels of late blight and pink rot developed in the trial. A single application of Confine at the labeled rate completely reduced (100%) both pink rot and late blight at four and eight months of storage.

5.1.1 Acceptable Efficacy Claims

The claim for suppression of pink rot and late blight on storage potatoes, when applied once as a post-harvest treatment at the dilution rate of 1:4.3 water, is supported. Data requirements pertaining to the efficacy of Confine after common storage periods have been satisfied, allowing for a conversion of the status of Confine from conditional to full registration.

5.2 Phytotoxicity to Host Plants

The registrant had previously indicated that the active ingredient contained in Confine may affect light-skinned potatoes. The use of Confine on light-skinned potatoes is now supported based on evidence from a related submission.

5.3 Economics

No market analysis was provided for this application.

5.4 Sustainability

5.4.1 Survey of Alternatives

Currently, there are no other products registered for the control/suppression of late blight or pink rot on stored potatoes in Canada.

5.4.2 Compatibility with Current Management Practices Including Integrated Pest Management

The use of Confine on stored potatoes will contribute to the management of potato late blight and pink rot of potatoes.

5.4.3 Information on the Occurrence or Possible Occurrence of the Development of Resistance

According to the Fungicide Resistance Action Committee, phosphonate fungicides (Group 33), such as Confine, present a low risk of pest resistance development. There are, however, some reports of *Phytopthora* spp. resistant to phosphonates. At this time, there are no resistance management concerns with the use since Confine will be applied only once per season. However, resistance management must be taken into consideration when assessing future potential amendments to the use pattern of phosphorous acid.

5.4.4 Contribution to Risk Reduction and Sustainability

Confine is a non-conventional product with a low risk of pest resistance development, which makes it a viable option for the post-harvest management of the high-risk pathogen *Phytophthora infestans*.

6.0 Pest Control Product Policy Considerations

For an assessment of the pest control product policy considerations, please refer to ERC2010-09 - *Mono- and Di-Potassium Salts of Phosphorous Acid.*

7.0 Summary

7.1 Human Health and Safety

The available information for mono- and di-potassium salts of phosphorous acid is adequate to qualitatively identify the toxicological hazards that may result from human exposure to mono- and di-potassium salts of phosphorous acid. Submitted information suggests that mono- and di-potassium salts of phosphorous acid is of low acute toxicity irrespective of the route of exposure and only minimally irritating to the eyes.

Occupational exposure is expected to be minimal resulting from the use pattern, method of application, and the application rate. Moreover, the precautionary statements on the product labels are sufficient to minimize any risk due to exposure of workers and bystanders.

Exposure to mono- and di-potassium salts of phosphorous acid from the diet or drinking water is not expected to be of concern.

7.2 Environmental Risk

Because mono- and di-potassium salts of phosphorous acid and the end-use product Confine are used post-harvest indoors, the risk to non-target organisms is considered to be negligible when used according to the label.

7.3 Value

Efficacy results showed that one application of phosphorous acid at the proposed rate suppressed late blight and pink rot in stored potatoes. Product efficacy was maintained after four and eight months of storage. The conversion of the status of Confine from conditional to full registration is supported.

8.0 Proposed Regulatory Decision

Health Canada's PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing full registration for the sale and use of Mono- and Di-Potassium Salts of Phosphorous Acid and Confine, containing the technical grade active ingredient mono- and di-potassium salts of phosphorous acid, for suppression of late blight and pink rot on harvested potato tubers.

An evaluation of available scientific information found that, under the approved conditions of use, the product has value and does not present an unacceptable risk to human health or the environment.

List of Abbreviations

GRAS	Generally Regarded As Safe
kg	kilogram
L	litre
PMRA	Pest Management Regulatory Agency
ppm	parts per million
USEPA	United States Environmental Protection Agency

Appendix I Tables and Figures

Table 1 Use (label) Claims Proposed by Applicant and Whether Acceptable or Unsupported

Crop	Disease Rates, Use Pattern	Accepted VSAD Claims
Stored potatoes	Pests: Pink rot (*P. erythroseptica*); late blight (*P. infestans*) Rate: 1:4.3 dilution; apply 2 liters of the mixture to 1000 kg of harvested potatoes Method of application: spray Application timing: post-harvest No. of applications: 1 (per season)	The claim for suppression of pink rot and late blight of storage potatoes after 4-8 months in storage is supported as proposed.

References

A. List of Studies/Information Submitted by Registrant

1.0 Value

1969195 2010, Impact of Post-Harvest Confine Applications on Potato Disease in Storage and Fry Colour Characteristics., DACO: 10.2.3.4